UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/301,766	04/29/99	WATANABE E	0020-4559P

002292 HM12/0510
BIRCH STEWART KOLASCH & BIRCH
P O BOX 747
FALLS CHURCH VA 22040-0747

EXAMINER	
ZAGHMOUT,O	
ART UNIT	**PAPER NUMBER**
1638	9

DATE MAILED: 05/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/301,766	Watanabe et al.
Examiner	**Group Art Unit**
Ousama Zaghmout	1638

☒ Responsive to communication(s) filed on *Feb 22, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-10 and 16-23* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-10 and 16-23* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3 and 8*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED OFFICE ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

2. A copy of the signed IDS (1449 form) is enclosed.

3. Status of claims:

Applicant's election without traverse of group I, claims 1-10, 16-23 in Paper No. 7 is acknowledged.

Claims 1-10, 16-23 are pending (Paper No. 7).

Claims 11-15, 24-27 have been canceled (Paper No.7).

Claim Rejections-35 U.S.C. 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

1. Claims 1- 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The raffinose synthase gene, as claimed, has the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. V. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 91980).

Amendment of the claim to change " A raffinose synthase gene" to -- An isolated raffinose synthase gene--would overcome the rejection.

2. Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The nucleic acid, as claimed, has the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. V. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 91980).

Amendment of the claim to change "A nucleic acid " to -- An isolated nucleic acid--would overcome the rejection.

Claim rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Ist paragraph

Claims 1, 16-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabled for isolation of nucleotide sequences from a number of plant species (e.g., SEQ ID NO: 1-8) and the expression of a nucleotide sequence in transgenic mustard (Examples 7-9) wherein said nucleotide sequence was isolated using primers (SEQ ID NO: 47 and 48), does not reasonably provide enablement for the isolation of other nucleotide sequences which are hybridizable to a nucleotide sequence claimed in claim 1 (e.g., SEQ ID:2). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The breadth of the claims are not commensurate in scope with the enabling support provided. The specification does not teach those skilled in the art if other nucleotide sequences that hybridize at low, medium, or high stringency would produce amino acid sequences encoding a raffinose synthase enzyme as defined in the specification. The specification does not give those skilled in the art guidance as to which, amino acids could be changed without changing the identity of the raffinose synthase enzyme as defined by its activity because a very small change in the amino acid sequence of a protein can result in a very large change in the structural-functional activity of a protein. Thus, those skilled in the art have to test at least 265^{265} amino acid sequences to enable the invention as claimed. This

would amount to undue experimentation. See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by " its physical or chemical properties" (e.g., DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. The Court found that for conception of a chemical compound (which term included genes) a mental picture of the structure or, if one is able to define its method of production, its physical or chemical properties or other distinguishing characteristics is required. Amgen's inventor did not have the necessary picture of the EPO gene until the gene had been isolated. A mere definition of biological properties was not enough since this was merely a wish to know the structure of material having the defined properties. In situations such as this the doctrine of "simultaneous conception and reduction to practice" applies. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Furthermore, the specification does not teach if the claimed sequences would enable the method as claimed to produce a raffinose synthase in transformants. The specification teaches only the transformation, not the expression of nucleotide sequences, which were isolated using primers (SEQ ID NO: 47 and 48) into a mustard plant. However, the

specification does not teach those skilled in the art if a raffinose synthase was produced these plants. The presentation of working examples showing that the claimed nucleotide sequence would produce raffinose synthase upon transformation into a plant is needed to enable the invention as claimed in light the unpredictability of maintaining the functional activity of a protein upon minor changes in its amino acid sequence as discussed above.

Taken together, the instant disclosure lacks the proper and sufficient guidance to enable the claims as set forth. Thus it is not readily predictable that the genetic modification specifically disclosed will work with other genes or other plants. Applicant has provided no specific guidance as to how to select genes which will give the desired effect or provided guidance with regard to selection of other plants and/or the technique to be used in the modification of these genetic modification of these plants. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not.

In view of the breadth of the claims, unpredictability, lack of guidance in the specification of the results as stated above, it is the examiner's position that one skilled in the art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentation.

2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-10, 16 and dependent claims 17-23 are rejected under 35 U.S.C. 112, second paragraph, as being vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 1 and dependent claims 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being vague for the recitation of " hybridizable" and 'stringent conditions" as it is not clear if the stringency of the hybridization condition is low, medium, or high.

2. Claims 1-10 and dependent claims 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being vague for the recitation of "represented by" as it is not clear if sequences presented in the claims are only examples of the sequences that are actually encompassed by the claims. The deletion of "represented by" and insertion of --as shown in-- or --as depicted in-- would obviate the rejection.

3. Claim 16 and dependent claims 19, 20 are rejected under 35 U.S.C. 112, second paragraph, as being vague for the recitation of " nucleic acid exhibiting promoter activity in a host cell" as it is not clear if the Applicants intend nucleic acid molecules such as intron, promoter, enhancer, transcription factor, subgenomic sequence, combination therefrom or other unknown regulatory sequences which exhibit promoter activity in a host cell.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 16, 18-19, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Castillo et al (Journal of Agricultural and Food Chemistry. Feb 1990. Vol. 38: 351-355).

The claims are drawn to raffinose synthase gene encompassed by sequences 1-10, as claimed. Subsequent claims are drawn to host cell containing said gene wherein the gene is joined to a nucleic acid exhibiting promoter activity in a host cell. The limitation "wherein the nucleic acid is introduced into a host cell" is being viewed by the Examiner as a process limitation which does not impart any change in the product.

Castillo et al teach the presence of raffinose synthase activity in the developing soybean seed (lines 2-3, column 1, page 354 under Discussion; see also Table 1, page 354)). The reference teaches partial purification of raffinose synthase from soybean seeds following treatment of crude extract with protamine sulfate which gave approximately 2-3-fold purification (Table 1). In addition, about 62% of the exchange reaction was recovered in the 30% ammonium sulfate fraction with an 8-fold increase in purification (paragraph 2, page 253). The partially purified enzyme taught by the reference would inherently contain an amino acid sequence encoded by the nucleic acid sequence claimed in this invention.

The raffinose synthase activity present in the plant taught by the reference is an indication that raffinose synthase gene contained in the plant is inherently present under a nucleic acid

exhibiting promoter activity, otherwise raffinose synthase activity would not have been observed.

The raffinose synthase gene which is inherently present in the host cell of the prior art reference appears to be the same as the product claimed by applicant because they appear to possess the same functional characteristics, i.e raffinose synthase activity. The production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art (claims 18-19,22). This is particularly true when the properties of the product are not changed by the process in an expected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 29222-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Since the Office does not have the facilities for examining and comparing applicants' raffinose synthase gene with the raffinose synthase gene of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the host cell of plant of the prior art does not possess the same material structural and functional characteristics of the claimed raffinose synthase gene). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Obviousness-type double patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA

1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 16-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-18, 30-36, 40-41, 43-44 of copending Application No. 08/992,914. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping in the scope. In that respect, the raffinose synthase gene as claimed in the co-pending Application No. 08/992,914 would encompass the nucleotide sequences encoding raffinose synthase claimed in the instant application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

May 2, 2000

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600